IS 5347-12 (1993): Requirements for orthopaedic implants, Part 12: Wrought cobalt-nickel-chromium molybdenum tungsten iron alloy [MHD 2: Orthopaedic Instruments, Implants and Accessories]

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IS 5347 (Part 12) : 1993
ISO 5832-8 : 1987
(Reaffirmed 1998)

भारतीय मानक

अस्थि अन्तर्रोपणो की अपेक्षाऐं

भाग 12 पिटवाँ कोबाल्ट-निकेल-क्रोमियम-मालिबडेनम-टंगस्टन-लोह मिश्रातु

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 12 WROUGHT COBALT-NICKEL-CHROMIUM-MOLYBDENUM-TUNGSTEN-IRON ALLOY

UDC 615·465·669·255·24·26·28·27·15·295

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

August 1993

Price Group 1

NATIONAL FOREWORD

This Indian Standard, which is identical with ISO 5832/8 : 1987 'Implants for surgery — Metallic materials — Part 8 : Wrought-cobalt-nickel-chromium-molybdenum-tungsten-iron alloy', issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee (MHD 2) and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 643 : 1983	IS 4748 : 1988 Method for estimating average grain size of metals (*first revision*)	Technically equivalent
ISO 6892 : 1984	IS 1608 : 1972 Method for tensile testing of steel products (*first revision*)	Technically equivalent

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 12 WROUGHT COBALT-NICKEL-CHROMIUM-MOLYBDENUM-TUNGSTEN-IRON ALLOY

1 Scope and field of application

This part of ISO 5832 specifies the characteristics of, and the corresponding test methods for, wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy for use in the manufacture of surgical implants.

NOTE — The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 References

ISO 643, *Steels — Micrographic determination of the ferritic or austenitic grain size.* [1)]

ISO 6892, *Metallic materials — Tensile testing.*

3 Chemical composition

When tested in accordance with the methods specified in clause 6, the heat analysis of the alloy shall comply with the chemical composition specified in table 1. The analysis of samples taken from products manufactured from the alloy shall also comply with table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)
Cobalt	Balance
Nickel	15,0 to 25,0
Chromium	18,0 to 22,0
Molybdenum	3,0 to 4,0
Tungsten	3,0 to 4,0
Iron	4,0 to 6,0
Titanium	0,5 to 3,50
Carbon	0,05 max.
Manganese	1,00 max.
Silicon	0,50 max.
Sulfur	0,010 max.

4 Microstructure

The microstructure[2)] shall be uniform and single-phased in the annealed condition. The grain size in the annealed condition, determined as specified in clause 6, shall be no coarser than grain size No. 5.

1) ISO 643 is given as a reference even though the material dealt with in this part of ISO 5832 is not iron-based.

2) For the determination of the microstructure, the following etching reagent may be used : 10 ml of nitric acid (ϱ_{20} 1,4 kg/l) plus 100 ml of hydrochloric acid (ϱ_{20} 1,19 kg/l) plus 0,3 ml of Vogel's Sparbeize plus 100 ml of distilled water.

5 Mechanical properties

The mechanical properties of this material can be altered by cold working and cold working plus ageing processes.

The tensile properties of the alloy, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

6 Test methods

The test methods to be used for determining compliance with the requirements of this part of ISO 5832 shall be those given in table 3.

Table 2 — Mechanical properties

Conditions	Tensile strength R_m min.	Proof stress of non-proportional elongation $R_{p0,2}$ min.	Percentage elongation after fracture** A min.	Percentage reduction of area Z min.
	N/mm²*	N/mm²*	%	%
Fully annealed	600	276	50	65
Cold worked or cold worked and aged				
Medium hard	1 000	827	18	50
Hard	1 310	1 172	12	45
Extra hard	1 580	1 310	5	35

* 1 N/mm² = 1 MPa

** Gauge length = $5{,}65\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area in square millimetres.

Table 3 — Test methods

Requirement	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ISO 643
Mechanical properties Tensile strength Proof stress of non-proportional elongation Percentage elongation after fracture Percentage reduction of area	5	ISO 6892

Standard Mark

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Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indin Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'. Comments on this Indian Standard may be sent to BIS giving the following reference:

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